

WHAT IS CLAIMED IS:

1                   1.       A method of treating a neoplasia in a mammal, said method  
2 comprising administering to said mammal a serum-stable nucleic acid-lipid particle  
3 comprising a nucleic acid portion that is fully encapsulated within the lipid portion,  
4 wherein said administration is by injection at an injection site that is distal to said  
5 neoplasia in said mammal.

1                   2.       A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, wherein said nucleic acid comprises an expressible gene.

1                   3.       A method of treating a neoplasia in a mammal in accordance with  
2 claim 2, wherein said expressible gene encodes a member selected from the group  
3 consisting of therapeutic polypeptides and therapeutic polynucleotides.

1                   4.       A method of treating a neoplasia in a mammal in accordance with  
2 claim 2, wherein said gene is exogenous.

1                   5.       A method of treating a neoplasia in a mammal in accordance with  
2 claim 3, wherein said gene is a member selected from the group consisting of genes  
3 encoding suicide enzymes, toxins and ribozymes.

1                   6.       A method of treating a neoplasia in a mammal in accordance with  
2 claim 2, wherein said gene encodes a member selected from the group consisting of  
3 herpes simplex virus thymidine kinase (HSV-TK), cytosine deaminase, xanthine-  
4 guaninephosphoribosyl transferase, purine nucleoside phosphorylase, cytochrome P450  
5 2B1 and analogs thereof.

1                   7.       A method of treating a neoplasia in a mammal in accordance with  
2 claim 2, wherein said gene is homologous.

1                   8.       A method of treating a neoplasia in a mammal in accordance with  
2 claim 2, wherein said gene encodes a member selected from the group consisting of  
3 proto-oncogenes, cytokines, immune stimulatory proteins and anti-angiogenic proteins.

1                   9.     A method of treating a neoplasia in a mammal in accordance with  
2 claim 2, wherein said gene is a member selected from the group consisting of IL-2, IL-12,  
3 IL-15 and GM-CSF.

1                   10.    A method of treating a neoplasia in a mammal in accordance with  
2 claim 2, wherein a therapeutically effective amount of said gene is generated at said  
3 neoplasia.

1                   11.    A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, wherein said nucleic acid-lipid particle comprises a protonatable lipid having a  
3 pKa in the range of about 4 to about 11.

1                   12.    A method of treating a neoplasia in a mammal in accordance with  
2 claim 11, wherein said protonatable lipid is a member selected from the group consisting  
3 of DODAC, DODAP, DODMA, DOTAP, DOTMA, DC-Chol, DMRIE, DSDAC and  
4 mixtures thereof.

1                   13.    A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, wherein said nucleic acid-lipid particle comprises a lipid conjugate that prevents  
3 aggregation during formulation.

1                   14.    A method of treating a neoplasia in a mammal in accordance with  
2 claim 13, wherein said lipid conjugate is a member selected from the group consisting of  
3 PEG-lipids and PAO-lipids.

1                   15.    A method of treating a neoplasia in a mammal in accordance with  
2 claim 13, wherein said lipid conjugate is reversibly associated with an outer lipid  
3 monolayer, and wherein said lipid conjugate exchanges out of said outer lipid monolayer  
4 at a rate faster than PEG-CerC20.

1                   16.    A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, wherein said nucleic acid-lipid particle is substantially devoid of detergents and  
3 organic solvents.

1                    17.     A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, wherein a therapeutically effective amount of said nucleic acid-lipid particle  
3 accumulates at said neoplasia.

1                    18.     A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, wherein a therapeutic effect is detected at the site of said neoplasia.

1                    19.     A method of treating a neoplasia in a mammal in accordance with  
2 claim 17, wherein said therapeutically effective amount comprises greater than about  
3 0.5% of an administered dose.

1                    20.     A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, wherein said nucleic acid-lipid particle has a diameter of about 50 nm to about  
3 200 nm.

1                    21.     A method of treating a neoplasia in a mammal in accordance with  
2 claim 20, wherein said nucleic acid-lipid particle has a diameter of about 60 nm to about  
3 130 nm.

1                    22.     A method of treating a neoplasia in a mammal in accordance with  
2 claim 20, wherein said nucleic acid-lipid particles are of a uniform size.

1                    23.     A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, wherein said nucleic acid-lipid particle has a nucleic acid to lipid ratio of greater  
3 than about 3 mg nucleic acid to mmole of lipid.

Sub E 1  
2                    24.     A method of treating a neoplasia in a mammal in accordance with  
3 claim 23, wherein said particle has a nucleic acid to lipid ratio of greater than about 14  
mg nucleic acid to mmole of lipid.

1                    25.     A method of treating a neoplasia in a mammal in accordance with  
2 claim 23, wherein said particle has a nucleic acid to lipid ratio of greater than about  
3 25 mg nucleic acid to mmole of lipid.

1                    26.     A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, wherein said nucleic acid remains at least 90% intact when said particle

Sub E1  
3 containing about 1 µg DNA is treated with about 100 U DNase 1 in digestion buffer at  
4 37°C for 30 min.

1 27. A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, further comprising administering a chemotherapeutic agent.

Sub E1  
1 28. A method of treating a neoplasia in a mammal in accordance with  
2 claim 1, wherein said administering is performed at least once per eight weeks.

1 29. A method of sensitizing a neoplastic cell to a compound, said  
2 method comprising:

3 a) transfecting said neoplastic cell with a serum-stable nucleic  
4 acid-lipid particle encoding a gene-product comprising a nucleic acid that is fully  
5 encapsulated within a lipid, wherein administration of said nucleic acid-lipid particle is by  
6 injection at an injection site that is distal to said neoplastic cell; and

7 b) delivering to said cell a first compound which is processed  
8 by said gene-product into a second compound, wherein said cell is more sensitive to said  
9 second compound than said first compound.

1 30. A method of sensitizing a neoplastic cell in accordance with  
2 claim 29 wherein said first compound is formulated in a lipid.

1 31. A method of sensitizing a neoplastic cell in accordance with  
2 claim 29 wherein said gene product is a member selected from the group consisting of  
3 therapeutic polypeptides and therapeutic polynucleotides.

1 32. A method of sensitizing a neoplastic cell in accordance with  
2 claim 29 wherein said gene product is a member selected from the group consisting of  
3 suicide enzymes, toxins and ribozymes.

1 33. A method of sensitizing a neoplastic cell in accordance with claim  
2 29 wherein said gene product is a member selected from the group consisting of herpes  
3 simplex virus thymidine kinase (HSV-TK), cytosine deaminase, xanthine-  
4 guaninephosphoribosyl transferase, purine nucleoside phosphorylase, cytochrome P450  
5 2B1 and analogs thereof.

- 1 34. A method of sensitizing a neoplastic cell in accordance with  
2 claim 29 wherein a therapeutic effect is detected at the site of said neoplasia cell.

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